

REMARKS

Favorable consideration and allowance are respectfully requested for claims 1-15 in view of the foregoing amendments and the following remarks.

New claim 15 is submitted herewith and relates to the sorting of the large-capturing particles into receptacles. Claim 9 is amended to indicate that the sorting is done into Petri dishes or microtiter plates. Support for these amendments is at least found in the specification at page 8, the end of paragraph [0014], which indicates that “these particles can be sorted into different layers (i.e., Petri dishes, 24-well culture plates, etc.).” These claims simply clarify that the sorted large particles must be placed in some form of a holding container or receptacle. Petri dishes and 24-well culture plates are examples of well-known and widely-used laboratory receptacles. Further, a person of skill in the art would understand by the language “Petri dishes, 24-well culture plates, etc.” that the list was not exhaustive and instead any suitable receptacle might be used for this sorting step.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The rejection of claims 1-14 under 35 U.S.C. § 112, second paragraph, as indefinite, is respectfully traversed.

The Office Action indicates that in claim 1, it is unclear whether or not the “large particle” and “other particles” are the same or different. As noted in the Office Action, claim 1 references the “large particle” in lines 2 and 5 and the

“other particles” in line 6. Claim 1 also references the “other particles” in lines 1 and 2. The preamble of claim 1, which reads “[a] process for isolating molecules, cells and *other particles* which are specifically bound to a *large particle* comprising:”, emphasis added, clearly indicates that the “other particles” and the “large particle” are different.

The Office Action also indicates that in claim 9, the language “other layers” is unclear. As currently amended, claim 9 no longer recited the phrase “other layers.”

For the foregoing reasons, withdrawal of the rejection of claims 1-14 is respectfully requested.

Rejections Under 35 U.S.C. § 102

The rejection of claims 1-14 under 35 U.S.C. § 102(b) over Burger, et al., U.S. Patent No. 4,904,581, is respectfully traversed.

The present invention relates to a method of isolating molecules, cells and other particles which are bound to a large particle by: (i) incubating a sample with large-capturing particles which are able to bind molecules, cells or other particles in the sample; (ii) analyzing the large capturing particles mixed with the sample; and (iii) sorting the large-capturing particles with bound molecules, cells or other particles. As described in the specification, the step of sorting the large-capturing particles is performed by “fluorescence specific stainings.” The specification further describes that the step of sorting can be done by a large-

particle sorting device such as the COPAS flow cytometry instrument (Union Biometrica, Boston, MA, USA), see page 7 of the specification, paragraph [0014].

The Burger reference relates to methods of detecting AIDS virus infection. One of the methods involves detecting the binding of antibodies to an antigen produced as a result of the infection. In particular, Burger does describe detecting cells based on flow cytometry, for instance in column 12, lines 28-46, however the technique is used to detect the presence of binding and not to sort out the cells with bound antibody.

The Office Action indicates that Burger describes sorting at col. 11, lines 1-5. This language, however, does not teach one skilled in the art to sort the mixture produced. Beginning at col. 10, line 63, Burger provides:

Members of a signal producing system and any ancillary materials may also be included in the aqueous medium, either concurrently or added subsequently so as to provide a detectable signal associated with the surface. The means for producing the detectable signal can involve the incorporation in the medium of labeled analyte or it may involve the use of a second monoclonal antibody having a label conjugated thereto. Separation and washing steps will be carried out as needed. The signal detected is related to the presence of a AIDS related infection.

The Office Action may be relying on the language “[s]eparation and washing steps will be carried out as needed.” However, this language does not

suggest to one skilled in the art that they might sort out the antibody-antigen complex from the mixture. Further, the language does not provide any suggestion as to how such a sorting technique might be performed. Rather, the language appears to suggest that it may be necessary to separate out or wash away the extraneous members of the signal producing system and ancillary materials in order to obtain a clear signal.

In fact, one performing the method of Burger would not be inclined to try to sort the mixture, since the invention is directed at detecting the presence of an AIDS virus. Further, the method taught by Burger is aimed at detecting an antigen produced by the presence of the viral pathogen HTLV III, and not the viral pathogen itself.

Not only does Burger not disclose or suggest the general method contemplated by the present invention, Burger does not teach the specific methods claimed in the present application. Considering claim 5, for instance, while Burger does disclose using multiple antibodies (3D8, 1E2 and 3G12) to detect the presence of the HTLV-III antigen, see col. 16, lines 25-46, it is not disclosed that these multiple antibodies are used with a single sample, as is recited in claim 5. Further, all of the antibodies are directed toward the same antigen, and therefore would not work to facilitate isolation/depletion of two or more different types of molecules, cells, or other particles as is recited in claim 5.

Further, Burger does not provide any indication of the use of large particles capable of binding multiple targets, as is provided in claim 6. The

Office Action indicates that this is taught in col. 10, lines 59-68. The cited language, to the contrary, describes use of a monoclonal antibody, which by definition, is intended to bind only a specific epitope.

Among other features, Burger does not teach the step of sorting, as is presently claimed. Therefore, withdrawal of the rejection of claims 1-14 is respectfully requested.

CONCLUSION

In view of the foregoing, the application is respectfully submitted to be in condition for allowance, and prompt favorable action thereon is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket No. 010770.49121US).

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Respectfully submitted,



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